Section 8- 510(k) Summary of Safety and Effectiveness

8.1 Statement

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and CFR 807.92

8.2 Submitter

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8.3 Company Contact

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8.4 Device Name

Proprietary Name: Haemonetics® Model 215 Automated Glycerolization / Deglycerolization System
Common Name: ACP 215
Classification Name: Processing System for Frozen Blood

8.5 Predicate Legally Marketed Devices

The Haemonetics ACP 215, which is the subject of this submission, is substantially equivalent to the previously cleared ACP 215 cleared via BK00002, BK030062, BK040077, and BK050006 by Haemonetics Corporation.

8.6 Device Description

The ACP 215 is an automated cell processing system intended to be used glycerolize and red blood cells.

8.7 Device Indications and Intended use	**Indications for use:** The ACP 215 is intended to glycerolize and deglycerolize red blood cells derived from whole blood that have been stored in any approved anticoagulant/additive solution for up to 6 days at 1-6°C prior to glycerolization. Red blood cells, derived from whole blood collections and non-leukoreduced, that have been collected and stored in CPDA-1, glycerolized using the ACP 215 and frozen at -65°C or colder and deglycerolized using the ACP 215 and stored in Haemonetics AS-3 at 1-6°C may be labeled for extended storage for 14 days. Red blood cells that have been collected and stored in CPD/AS-1, or CP2D/AS-3 (leukoreduced) or CPD/AS-5 (Leukoreduced or non-leukoreduced) glycerolized using the ACP 215, frozen at -65°C or colder, deglycerolized by the ACP 215, and stored in Haemonetics AS-3 at 1-6°C may be labeled for extended storage for 14 days. Whole blood derived red blood cells collected in any other anticoagulant / additive solution will be labeled with a 24-hour outdate. Red cells, non-leukoreduced, that were manually glycerolized using the 40% W/V Glycerol (Valeri Method) and frozen at -65°C or colder may be deglycerolized using the ACP 215 and labeled with a 24 hour outdate.

The following page contains a table comparing the new versus the predicate device.

8.1 TABLE OF SUSTANTIAL EQUIVALENCE

Characteristics	Predicate Device ACP 215 System	Proposed Device – ACP 215 System
Protocol	Automated Glycerolization/ Deglycerolization	Automated Glycerolization/ Deglycerolization
Hardware	ACP 215	ACP 215
Disposable	LN225, LN235-00 , LN236	LN225, LN226-00, LN235-00 , LN236
Washing Solution	12 %NaCl 0.9% NaCl/ 0.2gm Glucose	12 %NaCl 0.9% NaCl/ 0.2gm Glucose
Intended Use	The ACP 215 is intended to glycerolize and deglycerolize red blood cells derived from whole blood that have been stored in any approved anticoagulant/additive solution for up to 6 days at 1-6°C prior to glycerolization. Red blood cells, derived from whole blood collections and non-leukoreduced, that have been collected and stored in CPDA-1, glycerolized using the ACP 215 and frozen at -65°C or colder and deglycerolized using the ACP 215 and stored in Haemonetics AS-3 at 1-6°C may be labeled for extended storage for 14 days. In addition, red blood cells that have been collected and stored in CPD/AS-1, or CP2D/AS-3, leukoreduced, glycerolized using the ACP 215, frozen at -65°C or colder, deglycerolized by the ACP 215, and stored in Haemonetics AS-3 at 1-6°C may be labeled for extended storage for 14 days. Red blood cells collected in any other anticoagulant / additive solution will be labeled with a 24-hour outdate. Red cells, non-leukoreduced, that were manually glycerolized using the 40% W/V Glycerol (Valeri Method) and frozen at -65°C or colder may be deglycerolized using the ACP 215 and labeled with a 24 hour outdate.	The ACP 215 is intended to glycerolize and deglycerolize red blood cells derived from whole blood that have been stored in any approved anticoagulant/additive solution for up to 6 days at 1-6°C prior to glycerolization. Red blood cells, derived from whole blood collections and non-leukoreduced, that have been collected and stored in CPDA-1, glycerolized using the ACP 215 and frozen at -65°C or colder and deglycerolized using the ACP 215 and stored in Haemonetics AS-3 at 1-6°C may be labeled for extended storage for 14 days. Red blood cells that have been collected and stored in CPD/AS-1, or CP2D/AS-3 (leukoreduced) or CPD/AS-5 (Leukoreduced or non-leukoreduced) glycerolized using the ACP 215, frozen at -65°C or colder, deglycerolized by the ACP 215, and stored in Haemonetics AS-3 at 1-6°C may be labeled for extended storage for 14 days. Whole blood derived red blood cells collected in any other anticoagulant / additive solution will be labeled with a 24-hour outdate. Red cells, non-leukoreduced, that were manually glycerolized using the 40% W/V Glycerol (Valeri Method) and frozen at -65°C or colder may be deglycerolized using the ACP 215 and labeled with a 24 hour outdate
Product Quality	**Recovery:** 95% confidence that at least 90% units met the 80% minimum recovery **Hemolysis:** 95% confident that 95% of the units	**Recovery:** 95% confidence that at least 90% units met the 80% minimum recovery **Hemolysis:** 95% confident that 95% of the units

	demonstrate hemolysis of <1%. **<u>In Vivo Recovery:</u>** Sample mean in vivo 24-hour % recovery ≥ 75% with a standard deviation ≤ 9%, and with 95% confidence that the population mean ≥ 70%	demonstrate hemolysis of <1%. **<u>In Vivo Recovery:</u>** Sample mean in vivo 24-hour % recovery ≥ 75% with a standard deviation ≤ 9%, and with 95% confidence that the population mean ≥ 70%

Applicant _____ Date 4/14/06